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<p align="center">APPELLANTS' BRIEF</p> <p align="center">Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</p>	Attorney Docket No.	PALO-004
	Confirmation No.	8822
	First Named Inventor	YUN, ANTHONY JOONKYOO
	Application Number	10/748,976
	Filing Date	December 29, 2003
	Group Art Unit	3762
	Examiner Name	Kahelin, Michael William
	Title:	"TREATMENT OF FEMALE FERTILITY CONDITIONS THROUGH MODULATION OF THE AUTONOMIC NERVOUS SYSTEM"

Sir:

This Brief is filed in support of Appellants' appeal from the Examiner's Rejection dated January 28, 2009. No claims have been allowed. Claims 1-11, 17-20, and 39-42 are pending and appealed herein. A Notice of Appeal was filed on April 23, 2009. Therefore, this Appeal Brief is timely filed.

The Board of Appeals and Interferences has jurisdiction over this appeal pursuant to 35 U.S.C. §134.

The Commissioner is hereby authorized to charge deposit account number Deposit Account No. 50-0815, order number PALO-004, to cover the fee required under 37 C.F.R. §41.20(b)(2) for filing Appellants' Brief. In the unlikely event that the fee transmittal or other papers are separated from this document and/or other fees or relief are required, Appellants petition for such relief, including extensions of time, and authorize the Commissioner to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to deposit account number Deposit Account No. 50-0815, order number PALO-004.

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REAL PARTY IN INTEREST

The inventors named on this patent application assigned their entire rights to the invention to Palo Alto Investors.

RELATED APPEALS AND INTERFERENCES

There are currently no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal.

STATUS OF CLAIMS

The present application was filed on December 29, 2003 with Claims 1-38. During the course of prosecution, Claims 39-46 were added, Claims 15-16 and 31-38 were canceled and Claims 12-14 and 21-30 were withdrawn. Accordingly, Claims 1-11, 17-20, and 39-42 are pending and under examination in the present application, all of which are appealed herein.

STATUS OF AMENDMENTS

No amendments to the Claims were filed subsequent to issuance of the Final Rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is drawn to a method of treating a female subject known to suffer from a fertility condition. The method includes modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat the female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity.

Below is a description of each independent and separately argued independent and where support for each can be found in the specification.

Independent Claim 1 claims a method of treating a female subject for a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio of the subject in a manner effective to treat the female subject for the fertility condition, wherein the method further comprises determining the sympathetic activity /parasympathetic activity ratio at least prior to the modulation and performing the modulation of the at least one portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio (see, e.g., page 2, lines 3-9; p. 3, line 21 to p. 4, line 13; p. 7, lines 10-19; p. 35, line 8 to p. 35, line 2; p. 45, line 1 to p. 46, line 2; p. 50, lines 13-17; p. 52, line 26 to p. 53, line 6).

Claim 2 depends from Claim 1 and further specifies that the modulation is performed during at least one predetermined phase of the subject's menstrual cycle (see, e.g., page 37, lines 5-17; p. 44, lines 27-30; p. 47, line 27 to p. 48, line 19).

Claim 5 depends from Claim 1 and further specifies that the increase of the sympathetic activity/parasympathetic activity ratio comprises decreasing parasympathetic activity (see, e.g., page 4, line 14 to p. 5, line 2).

Claim 8 depends from Claim 1 and Claim 7, and further specifies that the modulation is localized to at least one pelvic nerve (see, e.g., page 37, line 27 to p. 38, line 16)

Claim 19 depends from Claim 1 and further specifies determining the ratio of Th-1 activity/Th-2 activity (see, e.g., page 6, line 21 to p. 7, line 9; and p. 45, line 1 to p. 46, line 2)

Claim 44 depends from Claims 1, 5 and 43 and further specifies decreasing parasympathetic activity by electrical inhibition which comprises ablation (see, e.g., p. 5, lines 13-20 and p. 12, lines 15-26).

Claim 45 depends from Claim 1, and further specifies that modulation is performed for a period of days (see, e.g., p. 37, lines 5-17).

Claim 46 depends from Claim 1, and further specifies that modulation is performed for a period of weeks (see, e.g., p. 37, lines 5-17).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,552,854).

II. Claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Bothe Loncar et al. (US Publication No. 2002/0188336).

III. Claims 5, 6, 11, 43 and 44 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. (USPN 6,832,114).

IV. Claim 8 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Mann et al. (US Publication No. 2002/0055761).

V. Claim 19 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Ideker, as applied to Claim 1 above, and further in view of Khan et al. (US Publication No. 2002/0064501).

ARGUMENT

I. Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 are patentable under 35 U.S.C. § 103(a) over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,552,854).

In the arguments set forth below, the Appellants will argue the rejected claims in Groups as follows:

Group I: Claims 1, 4, 7, 9, 10, 17, 18, 20, and 39-42

Group II: Claim 45

Group III: Claim 46

In the Final Office Action and the Advisory Action, the Examiner rejected Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 as being unpatentable under 35 U.S.C. § 103(a) over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,552,854).

In order to meet its burden in establishing a rejection under 35 U.S.C. §103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest all claim elements. See, e.g., KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740 (2007); Pharmastem Therapeutics v. Viacell et al., 491 F.3d 1342, 1360 (Fed. Cir. 2007); MPEP § 2143(A)(1). In addition to demonstrating that all elements were known in the prior art, the Office must also articulate a reason for combining the elements. See, e.g., KSR at 1741; Omegaflex, Inc. v. Parker-Hannifin Corp., 243 Fed. Appx. 592, 595-596 (Fed. Cir. 2007) citing KSR. Further, the Supreme Court in KSR also stated that that "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." KSR at

1740; emphasis added. As such, in addition to showing that all elements of a claim were known in the prior art and that one of ordinary skill in the art had a reason to combine them, the Office must also provide evidence that the combination would be a predicted success.

It is respectfully submitted that the Examiner's *prima facie* case of obviousness is deficient because the cited prior art fails to teach or suggest each and every claim limitation found in the claims of the instant application. Below are the contentions of the Appellants with respect to the grounds of rejection as stated above, with a separate subheading for each group of claims presented.

Group I: Claims 1, 4, 7, 9, 10, 17, 18, 20, and 39-42

The claims of Group I are directed to a method of treating a female subject known to suffer from a fertility condition. The claimed method includes modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat the female subject for the fertility condition. The claimed method also includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation, and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity.

The Office has rejected the claims of this group as being obvious over Rezaei in view of Ideker, and asserts that the cited references teach or suggest every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility

condition. The Appellants further submit that the cited references fail to teach or suggest determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation, and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, as is claimed.

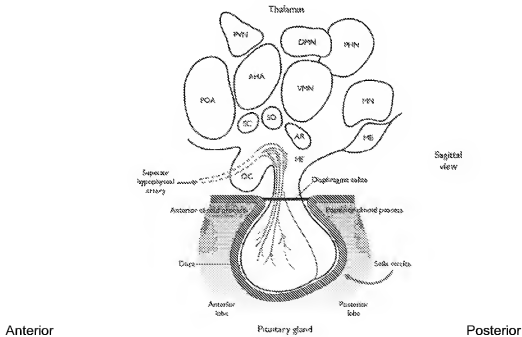
In maintaining the rejection, the Office alleges that Rezai's invention is capable of increasing the sympathetic/parasympathetic activity ratio of the subject. For evidence that hypothalamus stimulation will result in increasing the ratio, the Office cites Maillard (U.S. Patent 4,339,384). The Office further alleges that although Rezai does not disclose determining a ratio of sympathetic activity to parasympathetic activity, Ideker, et al. allegedly teach sensing a ratio of sympathetic and parasympathetic nervous system conduction (Final Office Action, p. 3-4).

The Appellants respectfully disagree with the position put forth by the Office. The Appellants maintain that neither Rezai nor Ideker contains the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. The disclosure in Rezai merely teaches stimulation of the hypothalamus for treatment of a wide variety of conditions. There is no disclosure in Rezai of a ratio of any kind, and there is no disclosure of increasing a sympathetic/parasympathetic ratio in a manner effective to treat a subject. The Office alleges that "Rezai does increase the sympathetic activity/parasympathetic activity ratio, regardless of whether this effect was realized at the time, as evidenced by Maillard (col. 8, lines 33-36)" (Final Office Action, p. 7).

However, the Appellants contend that the cited portion of Maillard merely states that "electric stimulation of the posterior hypothalamus induces an intense activation of the sympathetic system and of the dysrhythmias". Rezai, on the other hand, discloses on p. 1, col. 2, paragraph [0005]:

Specifically, the present invention relates to implanting a stimulator, which can be either an electrode or catheter, into a target site of a hypothalamic-associated circuitry, a hypothalamus, a division of a hypothalamus, or a nucleus of a hypothalamus to electrically and/or chemically stimulate the target site to modulate the target site to affect the hypothalamic-related condition.

In other words, the stimulation in Rezaei can be *any* part of the hypothalamus, not just the posterior hypothalamus. Maillard merely mentions stimulation of the "posterior hypothalamus", which is not otherwise specified. As seen in the diagram below, the posterior hypothalamus is just *one* area of the hypothalamus.



The anatomy of the hypothalamo-pituitary axis showing the major hypothalamic nuclei and the pituitary gland: Abbreviations: AHA, anterior hypothalamic area; AR, arcuate nucleus; DMN, dorsomedial nucleus; MB, mammillary body; ME, median eminence; MN, medial nucleus; OC, optic chiasm; PHN, posterior hypothalamic nucleus; POA, preoptic area; PVN, paraventricular nucleus; SCN, supraoptic nucleus; SO, supraoptic nucleus; VMN, ventromedial nucleus. From

<http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=endocrin&part=A1257&rendertype=box&id=A1272>

Therefore, the Office has not provided sufficient evidence that the methods in Rezai would *necessarily* result in an increase in the sympathetic activity/parasympathetic activity ratio, because the methods in Rezai are not limited to stimulation of the posterior hypothalamus. In fact, Rezai discloses stimulation of the preoptic nucleus for infertility (p. 7, Table VIII). Stimulation of the preoptic nucleus, shown in the anterior portion of the hypothalamus above, would therefore definitely *not* result in an increase in the sympathetic activity/parasympathetic activity ratio as the Office suggests. Furthermore, Rezai does not even specifically disclose stimulation of the sympathetic nervous system. There is therefore no disclosure in Rezai of increasing a sympathetic/parasympathetic ratio in a manner effective to treat a subject, and there is no evidence that the methods in Rezai would *necessarily* result in an increase in the sympathetic activity/parasympathetic activity ratio.

The Office acknowledges that Rezai does not disclose determining the sympathetic/parasympathetic ratio. The Office therefore relies on Ideker for this element. The Office states that Ideker is relied upon "for the teaching of determining sympathetic/ parasympathetic ratio balance as a particular type of "neuronal electrical activity...by afferent and efferent pathways that project to and from or communicate with the target site (Rezai, par. 0048)" " (Advisory Action, p. 2).

However, the Appellants maintain that Ideker is directed to a method for preventing arrhythmia by afferent nerve stimulation. To the extent that Ideker discloses determining the ratio of sympathetic nerve activity to parasympathetic nerve activity, it is for the purpose of detecting a high risk of arrhythmia (col. 1, lines 53 to 56). Further, in determining the ratio of sympathetic to parasympathetic nerve activity, Ideker discloses that it is a subject's heart rate variability that is measured (col. 3, lines 49 to 52). Additionally, to the extent that Ideker discloses stimulating a nerve it is an afferent nerve to the heart or central nervous system (col. 2, lines 60 to 62). Hence, there is no suggestion in Ideker of *increasing the sympathetic activity/parasympathetic activity ratio*

in a manner effective to treat a subject, and no disclosure of treating fertility. Therefore, the Appellants maintain that as neither Rezai nor Ideker teaches or suggests the element of increasing the sympathetic activity/parasympathetic activity ratio of a subject in a manner effective to treat a female subject for a fertility condition, the combination of the references fails to teach or suggest all the elements of the current claims.

Furthermore, the Office has not articulated a sufficient reason why one of skill in the art would use the method in Rezai with the ratio of Ideker, because Rezai discloses using only a simple measurement of neuronal activity, and not a ratio. The Office alleges that using Ideker's variable (sympathetic/parasympathetic ratio) in place of the "rate and pattern of neuronal activity" disclosed in Rezai is a "simple substitution" (Final Office Action, p. 8). The Office further alleges that "Ideker is cited as an example of using this particular type of neuronal electrical activity for closed loop control of autonomic-nervous-system-related stimulation" (Advisory Action, p. 3)

However, the Appellants contend that the "sensor signal" for the closed-loop feedback mechanism disclosed in Rezai is a simple measurement, such as synaptic potential (paragraphs [0047] and [0048]). Rezai in fact discloses a long list of potential "sensor signals", as follows:

"Such physiological activity to be detected is a physiological characteristic or function of the body, and includes, for example, body temperature regulation, blood pressure, metabolic activity, cerebral blood flow, pH levels, vital signs, galvanic skin responses, electrocardiogram, electroencephalogram, action potential conduction, and hormone, electrolyte, glucose or other chemical production." (see paragraph [0047], lines 14-21)

The list of "sensor signals" in Rezai consists of simple measurements, e.g., blood pressure, or electrocardiogram. There is no disclosure in Rezai of determining a ratio of neuronal activity, which would require a measure of sympathetic activity, a measure of parasympathetic activity, and then comparing the two measures to determine a ratio. In fact, Rezai even discloses that "if the hypothalamic-related condition is arrhythmias, bradycardia, or angina, then sensors may be placed on the

skin to measure electrocardiograms" (paragraph [0051], lines 17-19) In other words, *even if* the condition is an arrhythmia, as in Ideker, the suggested "feedback" in Rezai is a skin sensor to measure an electrocardiogram, i.e., a simple measurement of neuronal activity. There is simply no suggestion in Rezai of using a ratio of any kind.

In response to this argument, the Office has alleged that "the examiner is not relying in any way on Rezai's arrhythmia embodiment. Although combining various embodiments of Rezai with various embodiments of Ideker may or may not result in the claimed subject matter, the examiner is relying on Rezai's fertility-treating embodiment using closed-loop feedback of neuronal activity patterns" (Final Office Action, p. 8).

However, the Appellants contend that "[t]he Examiner has the initial burden of establishing a prima facie case of obviousness. See *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984); *In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976). The reasoning relied upon by the Examiner must not come solely from the description of the Appellants' invention in their Specification. If it does, the Examiner used impermissible hindsight when rejecting the claims. See *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984); *In re Rothermel*, 276 F.2d 393, 396 (CCPA 1960)." (See BPAI decision of 1/15/2009 *Ex parte Vogel*, Ognibene, Bench, and Peaslee; Appeal 2008-5921)

The Appellants maintain that the Office has not shown sufficient reason why one of ordinary skill in the art would have been led by the disclosure in Rezai's fertility-treating embodiment (using a feedback of a simple measurement of neuronal activity) with a ratio as disclosed in Ideker, which is furthermore a ratio for the purpose of detecting a high risk of arrhythmia. The Office has alleged that "Rezai further teach that fertility and arrhythmia conditions share a common pathway (par. 0002) that would suggest to an artisan of ordinary skill to consult the prior art of both fields for "neuronal electrical activity" indicators" (Advisory Action, p. 3)

However, the Appellants maintain that the cited paragraph in Rezai discloses:

"The hypothalamus is a central neurological structure composed of several sub-components that control a wide array of physiological functions in the human body. In particular, the hypothalamus modulates numerous fundamental body functions such as heart rate, body temperature, blood pressure, fluid and electrolyte balance, sleep, and food intake. In addition, the hypothalamus with the pituitary gland, is involved in endocrine activity...The hypothalamus also plays a role in regulating complex moods, such as anger, fear, sexual drive, placidity, and fatigue. Because of the hypothalamus' diverse and multiple roles, aberrant functioning of the hypothalamus or of structures and pathways that communicate with the hypothalamus can contribute to such varied conditions and disorders as arrhythmia, acromegaly and infertility." (Rezai, paragraph 0002)

The cited portion of Rezai merely confirms that hypothalamus is a central brain structure that controls a wide array of fundamental physiological functions. The Appellants contend that the Office has not provided a reason why one of ordinary skill in the art would combine the "fertility-treating embodiment" of Rezai with the ratio in Ideker, rather than use the "arrhythmia-treating embodiment" actually disclosed in Rezai, in which the suggested feedback is a skin sensor to measure an electrocardiogram (i.e., a simple measurement of neuronal activity). Further, if the Office is solely relying on "Rezai's fertility-treating embodiment using closed-loop feedback of neuronal activity patterns", this fertility-treating embodiment discloses stimulation of the preoptic nucleus in the *anterior* hypothalamus (p. 7, Table VIII) which would *not* result in an increase in the sympathetic activity/parasympathetic activity ratio.

Therefore, the Appellants maintain that the Office does not have support in Rezai's disclosure for the combination with Ideker. In fact, the reasoning relied upon by the Office for combining the two references appears to derive solely from the description of the Appellant's invention in their specification. The Office appears to be proposing a modification of the "fertility-treating embodiment" of Rezai's method by using the sympathetic activity/parasympathetic activity ratio for detecting a high risk of arrhythmia disclosed in Ideker, despite the fact that 1) Rezai does not disclose using a ratio of any kind; 2) in the case of an arrhythmia, Rezai teaches using a skin sensor

electrocardiogram, not a ratio, for the feedback loop; and 3) there is no evidence that Rezai's "fertility treating embodiment" would result in an increase in the sympathetic activity/parasympathetic activity ratio. The Examiner's rationale for modifying Rezai's method with the ratio of Ideker therefore appears to be based upon impermissible hindsight.

Therefore, as discussed above, the Appellants maintain that neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

Accordingly, the Appellants contend that a *prima facie* case of obviousness has not been established, because the combination of Rezai and Ideker does not teach or suggest all the elements of the rejected claims, and furthermore, the references have been improperly combined.

Group II: Claim 45

Claim 45 of Group II depends from Claim 1, which is directed to a method of treating a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion

of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity. Claim 45 further specifies that the modulation is performed for a period of days.

The Office has rejected the claims of this group as being obvious over Rezai in view of Ideker, and asserts that the cited reference teaches or suggests every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation is performed for a period of days, as is claimed.

In rejecting Claim 45, the Office alleges that neither Rezai nor Ideker disclose treatment for a period of days or weeks, however that it is well known to treat disorders of the human estrus cycle for a period of days to weeks (Final Office Action, p. 8). The Appellants maintain, however, that the disclosure in Rezai merely teaches that stimulation of the hypothalamus for a wide variety of conditions may be continuous or intermittent (paragraphs 0041 and 0042). There is no disclosure in Rezai of modulation for a period of days. The addition of Ideker does not remedy this deficiency, because Ideker also only discloses that stimulation may be performed continuously or intermittently to prevent the reoccurrence of an arrhythmia after delivery of the electric pulse (col. 3, lines 17-20).

Furthermore, as discussed above, the Appellants maintain that neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic*

activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition. Furthermore, neither Rezai nor Ideker teaches or suggests wherein the modulation is based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition, or wherein the modulation is performed for a period of days. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

Accordingly, the Appellants contend that a *prima facie* case of obviousness has not been established, because the combination of Rezai and Ideker does not teach or suggest all the elements of the rejected claims, and furthermore, the references have been improperly combined.

Group III: Claim 46

Claim 46 of Group III depends from Claim 1, which is directed to directed to a method of treating a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity. Claim 46 further specifies that the modulation is performed for a period of weeks.

The Office has rejected the claims of this group as being obvious over Rezai in view of Ideker, and asserts that the cited reference teaches or suggests every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation is performed for a period of weeks, as is claimed.

In rejecting Claim 46, the Office alleges that neither Rezai nor Ideker disclose treatment for a period of days or weeks, however that it is well known to treat disorders of the human estrus cycle for a period of days to weeks (Final Office Action, p. 8). The Appellants maintain, however, that the disclosure in Rezai merely teaches that stimulation of the hypothalamus for a wide variety of conditions may be continuous or intermittent (paragraphs 0041 and 0042). There is no disclosure in Rezai of modulation for a period of weeks. The addition of Ideker does not remedy this deficiency, because Ideker also only discloses that stimulation may be performed continuously or intermittently to prevent the reoccurrence of an arrhythmia after delivery of the electric pulse (col. 3, lines 17-20).

Furthermore, as discussed above, the Appellants maintain that neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. Furthermore, neither Rezai nor Ideker teaches or suggests wherein the modulation is based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition, or wherein the modulation is performed for a period of weeks. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

Accordingly, the Appellants contend that a *prima facie* case of obviousness has not been established, because the combination of Rezai and Ideker does not teach or suggest all the elements of the rejected claims, and furthermore, the references have been improperly combined.

In view of the above, the Appellants contend that Rezai in view of Ideker fail to make obvious Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 under 35 U.S.C. § 103(a) because the combination of references fail to teach all the elements of the rejected claims. Consequently, the Appellants respectfully request that these rejections be withdrawn.

II. Claims 2 and 3 are patentable under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Bothe Loncar et al. (US Publication No. 2002/0188336).

In the arguments set forth below, the Appellants will argue the rejected claims in a single group.

The claims of this group are directed to a method of treating a female subject known to suffer from a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation is performed during at least one predetermined phase of a subject's menstrual cycle.

The Office has rejected the claims of this group as being obvious over Rezai in

view of Ideker, or in the alternative, over Rezai and Ideker and further in view of Bothe Loncar, and asserts that the cited reference teach or suggest every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation is performed during at least one predetermined phase of a subject's menstrual cycle, as is claimed.

In rejecting the claims of this group, the Office has alleged that Rezai discloses the essential features of the claimed invention, including providing stimulation continuously (par. 0042), which would inherently provide modulation during the luteal phase. Alternatively, Rezai does not explicitly specify performing modulation during the luteal phase of the cycle, however Bothe Loncar teach providing ANS modulation during the luteal phase of the menstrual cycle (par. 0264). The Office alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by modulating the ANS during the luteal phase to provide the predictable results of enhancing the functions of the specific phase where pregnancy occurs (Final Office Action, p. 5)

However, as discussed above, neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a

manner effective to treat a female subject for a fertility condition. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

Therefore, the combination of Rezai and Ideker does not teach or suggest all the claim limitations. As Bothe Loncar is cited solely for its alleged disclosure of modulating the autonomic nervous system during the luteal phase of the menstrual cycle, it fails to remedy this deficiency.

Accordingly, a *prima facie* case of obviousness has not been established, because the combination of Rezai in view of Ideker and further in view of Bothe Loncar fails to teach or suggest all the claimed limitations, and furthermore, the references have been improperly combined.

In view of the above, the Appellants contend that Rezai in view of Ideker and further in view of Bothe Loncar fail to make obvious Claims 2 and 3 under 35 U.S.C. § 103(a) because the combination of references fail to teach all the elements of the rejected claims. Consequently, the Appellants respectfully request that these rejections be withdrawn.

III. Claims 5, 6, 11, 43 and 44 are patentable under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. (USPN 6,832,114).No. 2002/0188336).

In the arguments set forth below, the Appellants will argue the rejected claims in Groups as follows:

Group I: Claims 5, 6, 11 and 43

Group II: Claim 44

In the Final Office Action and the Advisory Action, the Examiner rejected Claims 5, 6, 11, 43 and 44 as being unpatentable under 35 U.S.C. § 103(a) over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,552,854) as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. (USPN 6,832,114).No. 2002/0188336).

It is respectfully submitted that the Examiner's *prima facie* case of obviousness is deficient because the cited prior art fails to teach or suggest each and every claim limitation found in the claims of the instant application. Below are the contentions of the Appellants with respect to the grounds of rejection as stated above, with a separate subheading for each group of claims presented.

Group I: Claims 5, 6, 11 and 43

The claims of this group depend from Claim 1, which is directed to a method of treating a female subject known to suffer from a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity. The claims of this group further specify decreasing parasympathetic activity, as in Claims 5 and 6, electrically inhibiting at least one portion of the autonomic nervous system, as in Claim 11, and electrically inhibiting at least one portion of the parasympathetic nervous system, as in Claim 43.

The Office has rejected the claims of this group as being obvious over Rezai in

view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. and asserts that the cited reference teaches or suggests every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation includes decreasing parasympathetic activity, as in Claims 5 and 6, electrically inhibiting at least one portion of the autonomic nervous system, as in Claim 11, or electrically inhibiting at least one portion of the parasympathetic nervous system, as in Claim 43.

In rejecting the claims of this group, the Office alleges that Rezai and Ideker disclose the essential features of the claimed invention except for "modifying the ratio by electrically decreasing parasympathetic activity or increasing sympathetic activity and decreasing sympathetic activity. Whitehurst teaches of ANS modulation achieved by electrically inhibiting parasympathetic stimulation and/or activating sympathetic stimulation (col. 18, line 60) to more accurately modulate the innervated organ" (Final Office Action, p. 6). The Office therefore alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai and Ideker's invention by providing ANS modulation by electrically inhibiting parasympathetic stimulation and/or activating sympathetic stimulation to provide the predictable results of more accurately modulating the innervated organ.

However, neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a*

female subject for a fertility condition. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason to combine Rezai with Ideker in the manner suggested.

The addition of Whitehurst et al. does not cure the deficiency of Rezai combined with Ideker. Whitehurst et al. disclose modulating a patient's pancreatic endocrine secretion by electrical stimulation to treat diabetes. However, Whitehurst et al. also does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject or modulating at least a portion of the autonomic nervous system to increase the sympathetic activity/parasympathetic activity ratio of the subject.

Therefore, the combination of Rezai and Ideker does not teach or suggest all the claim limitations. As Whitehurst is cited solely for its alleged disclosure of electrically inhibiting parasympathetic stimulation and/or activating sympathetic stimulation, it fails to remedy this deficiency.

Accordingly, a *prima facie* case of obviousness has not been established, because the combination of Rezai in view of Ideker and further in view of Whitehurst fails to teach or suggest all the claimed limitations, and furthermore, the references have been improperly combined.

Group II: Claim 44

Claim 44 depends from Claim 1, which is directed to a method of treating a female subject known to suffer from a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the

autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity. Claim 44 also depends from Claim 5, which further specifies decreasing parasympathetic activity, and Claim 43, which specifies electrically inhibiting at least one portion of the parasympathetic nervous system. Claim 44 further specifies that the electrical inhibition comprises ablation.

The Office has rejected Claim 44 as being obvious over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. and asserts that the cited reference teaches or suggests every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation includes decreasing parasympathetic activity by ablating at least one portion of the parasympathetic nervous system, as is claimed.

In rejecting the claims of this group, the Office alleges that Rezai and Ideker disclose the essential features of the claimed invention except for "modifying the ratio by electrically decreasing parasympathetic activity or increasing sympathetic activity and decreasing sympathetic activity. Whitehurst teaches of ANS modulation achieved by electrically inhibiting parasympathetic stimulation and/or activating sympathetic

stimulation (col. 18, line 60) to more accurately modulate the innervated organ" (Final Office Action, p. 6). The Office further alleges that "it is well known in the electrical arts therapy to inhibit neurological function by ablating specific nerves to provide the predictable result of permanently treating abnormal neurological behavior" The Office therefore alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai and Ideker's invention to inhibit neurological function by ablating specific nerves to provide the predictable result of permanently treating abnormal neurological behavior.

However, neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason to combine Rezai with Ideker in the manner suggested.

The Office cites Whitehurst for teaching "electrically inhibiting parasympathetic stimulation", further alleging that "it is well known in the electrical arts therapy to inhibit neurological function by ablating specific nerves to provide the predictable result of permanently treating abnormal neurological behavior". However, the Office has not provided a reference for this assertion. Furthermore, nowhere does Whitehurst teach the element electrical inhibition that comprises ablation, as in Claim 44. Additionally, Whitehurst does not suggest this element, because Whitehurst et al. only disclose modulating a patient's pancreatic endocrine secretion by electrical *stimulation* to treat diabetes. The Office has not provided any evidence that *ablation* of the nerves would work with the method in Whitehurst of electrical stimulation to treat diabetes.

Since the combination of Rezai, Ideker, or Whitehurst et al. does not disclose this claim element, the references, either alone or combined, do not teach or suggest all the claim limitations of Claim 44.

Accordingly, a *prima facie* case of obviousness has not been established, because the combination of Rezai in view of Ideker and further in view of Whitehurst fails to teach or suggest all the claimed limitations, and furthermore, the references have been improperly combined.

In view of the above, the Appellants contend that Rezai in view of Ideker and further in view of Whitehurst fail to make obvious Claims 5, 6, 11, 43 and 44 under 35 U.S.C. § 103(a) because the combination of references fail to teach all the elements of the rejected claims. Consequently, the Appellants respectfully request that these rejections be withdrawn.

IV. Claim 8 is patentable under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Mann et al. (US Publication No. 2002/0055761).

In the arguments set forth below, the Appellants will argue the rejected claims in a single group.

Claim 8 depends from Claim 1, which is directed to a method of treating a female subject known to suffer from a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio

of sympathetic activity to parasympathetic activity. Claim 8 further specifies that the modulation is localized to at least one pelvic nerve.

The Office has rejected the claims of this group as being obvious over Rezai in view of Ideker, and further in view of Mann, and asserts that the cited reference teach or suggest every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the modulation is localized to at least one pelvic nerve, as is claimed.

In rejecting the claims of this group, the Office has alleged that Rezai and Ideker disclose the essential features of the claimed invention except for stimulating the pelvic nerve. The Office cites Mann for teaching stimulation of a pelvic nerve (par. 0076) to more locally treat a fertility condition so as to not affect other systems of the body (abstract). The Office alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by stimulating a pelvic nerve to provide the predictable result of more locally treating a fertility condition so as to not affect other systems of the body (Final Office Action, p. 6)

However, as discussed above, neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a

manner effective to treat a female subject for a fertility condition. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

The Office cites Mann for teaching stimulation of a pelvic nerve "to treat a fertility condition", however Mann actually discloses stimulation of the pelvic nerve for treatment of incontinence, urgency, frequency, or pelvic pain, which is primarily directed to treatment of bladder conditions (abstract). There is no teaching in Mann of treatment of fertility conditions, and further nowhere does Mann suggest treatment for fertility conditions, because Mann is directed to treatment of bladder conditions. The Office has therefore not provided sufficient reason why one of skill in the art would combine a method of treating bladder disorders with the method of Rezai.

Furthermore, the combination of Rezai and Ideker does not teach or suggest all of the claim limitations. As Mann is cited solely for its alleged disclosure of stimulating the pelvic nerve, it fails to remedy this deficiency.

Accordingly, a *prima facie* case of obviousness has not been established, because the combination of Rezai in view of Ideker and further in view of Mann fails to teach or suggest all the claimed limitations, and furthermore, the references have been improperly combined.

In view of the above, the Appellants contend that Rezai in view of Ideker and further in view of Mann fail to make obvious Claim 8 under 35 U.S.C. § 103(a) because the combination of references fail to teach all the elements of the rejected claims. Consequently, the Appellants respectfully request that these rejections be withdrawn.

V. Claim 19 is patentable under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, and further in view of Khan et al. (US Publication No. 2002/0064501).

In the arguments set forth below, the Appellants will argue the rejected claims in a single group.

Claim 19 depends from Claim 1, which is directed to a method of treating a female subject known to suffer from a fertility condition. The method includes providing a female subject known to suffer from a fertility condition, and modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for the fertility condition. The method further includes determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity. Claim 19 further specifies determining the ratio of Th-1 activity/Th-2 activity.

The Office has rejected the claims of this group as being obvious over Rezai in view of Ideker, and further in view of Khan, and asserts that the cited reference teaches or suggests every element of the claims.

For the reasons detailed below, the Appellants submit that the cited references fail to make obvious the rejected claims. Specifically, the Appellants submit that the cited references fail to teach or suggest the elements of increasing the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition, and determining the ratio of sympathetic activity to parasympathetic activity prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined ratio of sympathetic activity to parasympathetic activity, wherein the method further comprises determining the ratio of Th-1 activity/Th-2 activity., as is claimed.

In rejecting the claims of this group, the Office has alleged that Rezai and Ideker disclose the essential features of the claimed invention except for determining the ratio of Th-1 to Th-2. The Office cites Khan for teaching regulating the Th1/Th2 ratio to facilitate fertility where improved implantation is required. The Office alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by determining the ratio of Th-1 to Th-2 to provide the predictable results of further facilitating fertility (Final Office Action, p. 7)

However, neither Rezai nor Ideker teaches or suggests the element of *increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition*. Furthermore, neither Rezai nor Ideker teaches or suggests modulation of at least one portion of the autonomic nervous system based on a *determined sympathetic activity/parasympathetic activity ratio* in a manner effective to treat a female subject for a fertility condition. The combination therefore does not contain all the elements of the claimed invention, and does not render the claimed invention obvious. In addition, the Office has not articulated a sufficient reason why one skilled in the art would have modified the method in Rezai with the ratio in Ideker.

Therefore, the combination of Rezai and Ideker does not teach or suggest all the claim limitations. As Khan is cited solely for its alleged disclosure of regulating the Th-1/Th-2 ratio, it fails to remedy this deficiency.

Accordingly, a *prima facie* case of obviousness has not been established, because the combination of Rezai in view of Ideker and further in view of Khan fails to teach or suggest all the claimed limitations, and furthermore, the references have been improperly combined.

In view of the above, the Appellants contend that Rezai in view of Ideker and further in view of Khan fail to make obvious Claim 19 under 35 U.S.C. § 103(a)

because the combination of references fail to teach all the elements of the rejected claims. Consequently, the Appellants respectfully request that these rejections be withdrawn.

SUMMARY

I. Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 are not obvious under 35 U.S.C. § 103(a) over Rezai (US Publication No. 2005/0065574) in view of Ideker et al. (5,552,854) because the combination of references fails to teach or suggest each and every element of this set of claims.

II. Claims 2 and 3 are not obvious under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Bothe Loncar et al. (US Publication No. 2002/0188336) because the combination of references fails to teach or suggest each and every element of this set of claims.

III. Claims 5, 6, 11, 43 and 44 are not obvious under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Whitehurst et al. (USPN 6,832,114). No. 2002/0188336) because the combination of references fails to teach or suggest each and every element of this set of claims.

IV. Claim 8 is not obvious under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, or, in the alternative, over Rezai and Ideker and further in view of Mann et al. (US Publication No. 2002/0055761) because the combination of references fails to teach or suggest each and every element of this claim.

V. Claim 19 is not obvious under 35 U.S.C. § 103(a) over Rezai in view of Ideker, as applied to Claim 1 above, and further in view of Khan et al. (US Publication No.

2002/0064501) because the combination of references fails to teach or suggest each and every element of this claim.

RELIEF REQUESTED

The Appellants respectfully request that the rejections of Claims 1-11, 17-20, and 39-42 under 35 U.S.C. §103(a) be reversed, and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

Date: June 24, 2009

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CLAIMS APPENDIX

1. A method of treating a female subject for a fertility condition, said method comprising:
 - providing a female subject known to suffer from said fertility condition; and
 - modulating at least a portion of the autonomic nervous system of said female subject to increase the sympathetic activity/parasympathetic activity ratio of said subject in a manner effective to treat said female subject for said fertility condition, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.
2. The method of Claim 1, wherein said modulation is performed during at least one predetermined phase of said subject's menstrual cycle.
3. The method of Claim 2, wherein said predetermined phase is the luteal phase.
4. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity.
5. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises decreasing parasympathetic activity.
6. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity and decreasing parasympathetic activity.

7. The method of Claim 1, wherein said modulation is localized.
8. The method of Claim 7, wherein said modulation is localized to at least one pelvic nerve.
9. The method of Claim 1, wherein said modulation is accomplished by at least applying electrical energy to said at least one portion of said autonomic nervous system.
10. The method of Claim 9, wherein said application of electrical energy comprises electrically increasing activity in at least one portion of said autonomic nervous system.
11. The method of Claim 9, wherein said application of electrical energy comprises electrically inhibiting activity in at least one portion of said autonomic nervous system.
17. The method of Claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least during said modulation.
18. The method of Claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least following said modulation.
19. The method of Claim 1, further comprising determining the ratio of Th-1 activity/Th-2 activity.
20. The method of Claim 1, wherein said fertility condition is infertility.

39. The method of Claim 7, wherein said modulation is localized to an area of the autonomic nervous system selected from the group consisting of pre-ganglionic nerve fibers, post-ganglionic nerve fibers, ganglionic structures, efferent nerve fibers, and afferent nerve fibers.

40. The method of Claim 1, wherein said sympathetic activity/parasympathetic activity ratio is determined by sensing conduction in at least a portion of the sympathetic and/or parasympathetic nervous system.

41. The method according to Claim 1, wherein said modulation comprises an implanted electrical energy delivering device.

42. The method according to Claim 41, wherein said implanted device is an electrode.

43. The method according to Claim 5, wherein said decrease in parasympathetic activity comprises electrical inhibition of at least one portion of the parasympathetic nervous system.

44. The method according to Claim 43, wherein said electrical inhibition comprises ablation.

45. The method according to Claim 1, wherein said modulation is performed for a period of days.

46. The method according to Claim 1, wherein said modulation is performed for a period of weeks.

EVIDENCE APPENDIX

No evidence that qualifies under this heading has been submitted during the prosecution of this application, and as such it is left blank.

RELATED PROCEEDINGS APPENDIX

As stated in the *Related Appeals and Interferences* section above, there are no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal. As such this section is left blank.